TAB A

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte THOMAS J. WHALEN II, CHINH N. TRAN, NOAH M. ROTH, and RICHARD J. GREFF

Appeal 2007-4423
Application 10/281,142
Technology Center 1600

Decided: July 23, 2008

Before MICHAEL R. FLEMING, *Chief Administrative Patent Judge*, and SALLY G. LANE, ERIC GRIMES, RICHARD M. LEBOVITZ, and FRANCISCO C. PRATS, *Administrative Patent Judges*.

GRIMES, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 involving claims to a composition for embolizing an aneurysm, which the Examiner has rejected for anticipation, obviousness, and obviousness-type double patenting. We have jurisdiction under 35 U.S.C. § 6(b). We reverse.

STATEMENT OF THE CASE

The Specification states that "[e]mbolizing compositions (embolic compositions) heretofore disclosed in the art include those comprising a biocompatible polymer, a biocompatible solvent and a contrast agent which allowed visualization of the *in vivo* delivery of the composition" (Spec. 3). "Such compositions typically contain no more than about 8 weight percent of biocompatible polymer based on the weight of the total composition" (*id.*).

The Specification states that prior art embolic compositions had the drawback that "upon ejection of the embolic composition in a vascular site, the coherent mass subsequently formed was often distal and not proximate the ejection port of the catheter. Moreover, upon solidification, the solid mass formed was often linear in shape (i.e., having a 'string shape')." (*Id.*) This property of the prior art compositions is said to lead to difficulty in site-specific delivery of the embolic composition, and the danger that fragments of the solidified composition will embolize an artery or "lodg[e] at undesired locations in the vasculature" (*id.*).

The Specification discloses that "formation of a solid non-migratory mass having a substantially contiguous or 'ball' shape can be achieved by use of embolic compositions . . . [having] a viscosity of at least 150 cSt at 40° C" (*id.*).[1] According to the Specification, "the viscosity of these compositions is significantly higher than those containing 8 weight percent polymer, thereby rendering it difficult to employ conventional delivery

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[1] Viscosity can be measured in units of centiStokes (cSt) or centipoise (App. Br. 6).

means (e.g., syringe). . . . However, delivery means such as the threaded syringes described [in two provisional patent applications] now renders the use of these highly viscous compositions practical." (*Id.* at 4.)

Claims 1-17 are pending and on appeal. Claim 1 is representative and reads as follows:

1. A composition capable of embolizing an aneurysm at a vascular site comprising:

(a) a biocompatible polymer;

(b) a biocompatible contrast agent wherein a sufficient amount of said contrast agent is employed in said composition to effect visualization *in vivo*; and

(c) a biocompatible solvent which solubilizes said biocompatible polymer

wherein a sufficient amount of said polymer are [sic] employed in said composition such that, upon delivery to a vascular site, a polymer precipitate forms which embolizes said vascular site; and

further wherein the biocompatible polymer has a molecular weight sufficient to impart to the composition a viscosity of at least about 150 cSt at 40° C.

The components recited in claim 1 – biocompatible polymer, biocompatible contrast agent, and biocompatible solvent – are the same as those in known embolic compositions (Spec. 3). Thus, if claim 1 differs from the prior art, it is by virtue of the limitation that "the biocompatible polymer has a molecular weight sufficient to impart to the composition a viscosity of at least about 150 cSt at 40° C." Claim 2, the only other independent claim on appeal, also includes this limitation.

As we interpret it, this limitation requires only that the claimed composition have "a viscosity of at least about 150 cSt at 40° C." Although the claim also refers to the molecular weight of the polymer in the

composition, that reference does not limit the claim: If a composition comprises the recited polymer and has the recited viscosity, then the polymer necessarily "has a molecular weight sufficient to impart" the resulting viscosity, at whatever concentration of polymer is present.

The Examiner has rejected the claims as follows:

• Claims 1-17 stand rejected for obviousness-type double patenting based on claims 1-5 of Greff '568,[2] claims 1-46 of Evans,[3] claims 1-6 of Greff '508,[4] and claims 1-6 of Greff '767;[5]

• Claims 1-13 and 15-17 stand rejected under 35 U.S.C. § 103 as obvious in view of Evans;

• Claims 1-17 stand rejected under 35 U.S.C. § 103 as obvious in view of Greff '767; and

• Claims 1-6, 9, 10, and 14-17 stand rejected under 35 U.S.C. §§ 102(b) or 103 as anticipated by or obvious in view of Taki.[6]

DOUBLE PATENTING

The Double Patenting Issue

Claims 1-17 stand rejected for obviousness-type double patenting based on claims 1-5 of Greff '568, claims 1-46 of Evans, claims 1-6 of Greff '508, and claims 1-6 of Greff '767.[7] The Examiner's position is:

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[2] Greff et al., U.S. Patent 5,580,568, issued Dec. 3, 1996.
[3] Evans et al., U.S. Patent 5,695,480, issued Dec. 9, 1997.
[4] Greff et al., U.S. Patent 5,581,508, issued Dec. 22, 1998.
[5] Greff et al., U.S. Patent 5,667,767, issued Sept. 16, 1997.
[6] Taki et al., "A new liquid material for embolization of arteriovenous malformations," 11 *AJNR, Amer. Journal of Neuroradiology* 163 (1990).
[7] In the Answer, the Examiner also rejected claims 1-17 based on claims 1-15 of U.S. Patent 6,531,111 (Ans. 4). However, Appellants have filed a

> both the patented claims and the instant pending claims are directed to compositions comprising a biocompatible polymer, a biocompatible contrast agent and a biocompatible solvent. Therefore, each set of the patented claim[s] anticipates the scope of the pending claim[s]. Accordingly, it would have been obvious to one of ordinary skill in the art at the time of invention to practice the pending claims when in possession of the patented claims. Thus, the pending claims are obvious variants of the patented claims.

(Ans. 4.)

Appellants contend that "[t]here is no teaching of viscosity in any of Claim 1-5 of the '568 patent" (App. Br. 11); "[t]here is no teaching, in either the specification or the claims of [Evans], of viscosities of 150 centiStokes at 40°C" (*id.* at 12); "it is unclear why Claims 1-17 [sic] of [Greff '508] would motivate one skilled in the art to make and use the high viscosity embolic composition of the claims on Appeal" (*id.* at 13); and "for the same reasons noted for the '508 patent, the rejection of Claims 1-17 . . . over Claims 1-6 of the '767 patent is in error" (*id.*).

In view of these conflicting positions, the double-patenting issue presented is: Are the rejected claims directed to a composition that is an obvious variant of the compositions claimed in Greff '568, Evans, Greff '508, or Greff '767?

Findings of Fact Relating to Double Patenting

FF1. Claim 1 of Greff '568 is directed to a composition comprising:

(a) from about 2.5 to about 8 weight percent of a cellulose diacetate having an acetyl content of from about 31 to about 40 weight percent;

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terminal disclaimer with respect to the '111 patent (terminal disclaimer received July 19, 2004) so that basis of the rejection has been overcome.

(b) from about 10 to about 40 weight percent of a water insoluble contrast agent selected from the group consisting of tantalum, tantalum oxide and barium sulfate;

(c) from about 52 to about 87.5 weight percent of a biocompatible solvent

wherein the weight percent of the cellulose diacetate, water insoluble contrast agent and biocompatible solvent is based on the total weight of the complete composition.

(Greff '568, col. 9, ll. 37-50.)

FF2. Claim 1 of Evans is directed to a composition comprising:

(a) from about 2.5 to about 8.0 weight percent of a biocompatible polymer;

(b) from about 10 to about 40 weight percent of a water insoluble, biocompatible contrast agent having an average particle size of about 10 μm or less; and

(c) from about 52 to about 87.5 weight percent of a biocompatible solvent

wherein the weight percent of the polymer, contrast agent and biocompatible solvent is based on the total weight of the complete composition.

(Evans, col. 11, ll. 47-58.)

FF3. Claim 1 of Greff '508 is directed to a composition comprising:

(a) from about 2.5 to about 8.0 weight percent of an ethylene vinyl alcohol copolymer;

(b) from about 20 to about 40 weight percent of a water insoluble contrast agent selected from the group consisting of tantalum, tantalum oxide and barium sulfate;

(c) from about 52 to about 87.5 weight percent of a biocompatible solvent

wherein the weight percent of each of the components is based on the total weight of the complete composition.

(Greff '508, col. 10, ll. 7-16.)

FF4. Claim 1 of Greff '767 is directed to a composition comprising:

(a) from about 2.5 to about 8.0 weight percent of an ethylene vinyl alcohol copolymer;

(b) from about 10 to about 40 weight percent of a water insoluble contrast agent selected from the group consisting of tantalum, tantalum oxide and barium sulfate;

(c) from about 52 to about 87.5 weight percent of a biocompatible solvent

wherein the weight percent of each of the components is based on the total weight of the complete composition.

(Greff '767, col. 9, ll. 37-50.)

FF5. Claims 1-5 of Greff '568, claims 1-46 of Evans, claims 1-6 of Greff '508, and claims 1-6 of Greff '767 do not limit the claimed compositions to those having a particular viscosity, and therefore encompass compositions having the components recited in those claims, in the recited concentrations, regardless of the viscosity of the resulting compositions.

FF6. The Examiner has not pointed to any evidence showing that any composition encompassed by claims 1-5 of Greff '568, claims 1-46 of Evans, claims 1-6 of Greff '508, or claims 1-6 of Greff '767 would inherently have a viscosity of at least about 150 cSt at 40° C.

Discussion of the Double Patenting Issue

We conclude that the Examiner has not shown that the composition of the claims on appeal is an obvious variant of the compositions of claims 1-5 of Greff '568, claims 1-46 of Evans, claims 1-6 of Greff '508, or claims 1-6 of Greff '767.

The analyses for obviousness under 35 U.S.C. § 103 and obviousness-type double patenting are not identical; for one thing, "[t]he objects of comparison are very different: Obviousness compares claimed subject matter to the prior art; nonstatutory double patenting compares claims in an

earlier patent to claims in a later patent or application." *Geneva Pharms., Inc. v. GlaxoSmithKline PLC*, 349 F.3d 1373, 1378 n.1 (Fed. Cir. 2003). The purpose of an obviousness-type double patenting rejection is "to prevent an unjustified extension of the term of the right to exclude granted by a patent by allowing a second patent claiming an obvious variant of the same invention to issue to the same owner later." *In re Berg*, 140 F.3d 1428, 1431 (Fed. Cir. 1998).

Here, all of the claims cited by the Examiner are limited to compositions containing less than about 8 weight percent polymer (FF1 to FF4). The instant Specification states that known embolic compositions typically contained less than about 8 weight percent polymer (Spec. 3) and that such compositions often formed undesirable "string shaped" masses (*id.*).

The Examiner has not directed us to evidence sufficient to show that any composition encompassed by the relied-upon patented claims – with less than about 8 weight percent polymer – would have a viscosity of 150 cSt at 40° C. Therefore, the Examiner's finding that the relied-upon patented claims anticipate the claims on appeal is not supported by the evidence.

The Examiner has not provided any other reasoned, fact-based explanation supported by the evidence of record to justify a conclusion that the compositions defined by the claims on appeal are obvious variants of the compositions of claims 1-5 of Greff '568, claims 1-46 of Evans, claims 1-6 of Greff '508, or claims 1-6 of Greff '767. We therefore reverse the rejections for obviousness-type double patenting.

REJECTIONS BASED ON THE PRIOR ART

The Obviousness and 102(b)/103 Issues

The Examiner finds that the compositions taught by Evans and Taki "inherently possess the same viscosity" as the claimed composition because they "comprise similar components[s] used in overlapping ranges of concentrations as those claimed" (Ans. 5-6; see also *id.* at 7). Alternatively, the Examiner concludes that the claimed compositions would have been obvious in view of the compositions taught by Evans, Greff '767, and Taki because "it would have been prima facie obvious to optimize the viscosity range of [the known] compositions by routine experimentation" (*id.* at 6, 7).

Appellants argue that Evans, Greff '767, and Taki refer to viscosity only in passing and when they do, they indicate that the disclosed compositions should have a viscosity well under 150 cSt (Evans and Greff '767) or are of "low viscosity" (Taki) and it is "unclear why [the prior art disclosures] would motivate one skilled in the art to make and use [a] high viscosity embolic composition" (App. Br. 12, 13-14, 15-16).

In view of these conflicting positions, the issue presented with respect to patentability over the cited prior art is: Do the disclosures of Evans, Greff '767, or Taki anticipate, or would they have rendered obvious, the claimed compositions to those of ordinary skill in the art?

Findings of Fact Relating to the Prior Art Rejections

FF7. The Examiner finds that "Evans' compositions have a viscosity of less than 60 centipoise at 20° C (see col 5, lines 37-43). Accordingly, Evans anticipates the limitations of the instant claims." (Ans. 5.)

FF8. The Examiner finds that "[a]lthough Evans does not specifically recite the instantly claimed viscosity of 150 cSt at 40° C . . . , Examiner takes the position that compositions disclosed by Evans inherently possess the same viscosity . . . as the instantly claimed invention, because Evans' compositions comprise similar component[s] used in overlapping ranges of concentrations" (Ans. 5-6).

FF9. The Examiner finds that a person of ordinary skill in the art "would have been motivated to optimize the viscosity of the Evans' final formulation, because he would have had a reasonable expectation of success in achieving the safest clinical outcome and avoiding transvenous passage" of the embolizing composition (Ans. 6).

FF10. The Examiner relies on the same reasoning in the rejections based on Greff '767 and Taki (Ans. 6-8).

FF11. Evans teaches compositions comprising a biocompatible polymer (2.5-8 wt %), a biocompatible contrast agent (10-40 wt %), and a biocompatible solvent (52-87.5 wt %) (Evans, col. 3, ll. 32-43).

FF12. Evans teaches that one preferred composition "has a viscosity equal to or less than 60 centipoise at 20° C" (Evans, col. 5, ll. 39-43).

FF13. According to Appellants, units of poise (or centipoise) are related to units of Stokes (or centiStokes) according to the equation Poise = Stokes x density (App. Br. 6).

FF14. The Examiner has not disputed that Poise = Stokes x density.

FF15. According to Appellants, "[f]or Newtonian fluids, it is well understood that viscosity decreases as temperature increases" (App. Br. 7).

FF16. The Examiner has not disputed that viscosity decreases as temperature increases.

FF17. Evans discloses that "all other factors being equal, copolymers having a lower molecular weight will impart a lower viscosity to the composition as compared to higher molecular weight copolymers. Accordingly, adjustment of the viscosity of the composition as necessary for catheter delivery can be readily achieved by mere adjustment of the molecular weight of the copolymer composition." (Evans, col. 5, ll. 44-50.)

FF18. Greff '767 teaches compositions comprising an ethylene vinyl alcohol copolymer (2.5-8 wt %), a contrast agent that is tantalum, tantalum oxide or barium sulfate (10-40 wt %), and a biocompatible solvent (52-87.5 wt %) (Greff '767, col. 3, ll. 37-48).

FF19. Greff '767 teaches that a composition comprising 6.8 weight percent of ethylene vinyl alcohol copolymer ("EVOH") in dimethyl sulfoxide ("DMSO") has a viscosity of approximately 60 centipoise at 20° C (Greff '767, col. 9, ll. 28-31).

FF20. Greff '767 teaches that addition of 38.5 weight percent metrizamide (a contrast agent; Greff '767, col. 9, ll. 4-6) to the composition of FF19 increased its viscosity to approximately 145 centipoise at 20° C (*id.* at col. 9, ll. 31-34).

FF21. Greff '767 teaches that addition of 35 weight percent tantalum or barium sulfate to a composition similar to that of FF19 did not materially alter its viscosity (Greff '767, col. 9, ll. 35-37).

FF22. Greff '767 states that the purpose of the compositions referred to in FF19 to FF21 was to "illustrate that certain embolizing agent/contrast

agent combinations provide for physical properties which make injection of the combination into vascular sites significantly more difficult" (Greff '767, col. 9, ll. 24-27).

FF23. Taki teaches an embolizing composition containing "5 g of solid ethylene vinyl alcohol copolymer (EVAL) and 35 g of powder metrizamide dissolved in 60 g of dimethyl sulfoxide (DMSO) as a solvent" (Taki 163).

FF24. Taki teaches that the "EVAL and DMSO mixture was of low viscosity and could be easily injected through the narrow lumen of the microballoon catheter, which was 150 cm in length" (Taki 168).

Discussion of the Obviousness and 102(b)/103 Issues

We determine that the Examiner has not made out a prima facie case that the claimed compositions are anticipated by Taki or would have been obvious in view of any of Evans, Greff '767, or Taki.

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros., Inc. v. Union Oil Co.*, 814 F.2d 628, 631 (Fed. Cir. 1987). None of the references relied on by the Examiner expressly describes an embolizing composition having a viscosity of at least 150 cSt at 40° C as required by claim 1.

The Examiner has not provided an adequate basis – based on evidence or scientific reasoning – to support the finding that the "compositions disclosed by Evans inherently possess the same viscosity . . . as the instantly claimed invention" (FF8, Ans. 5-6). The Examiner reasons that "Evans' compositions comprise similar component[s] used in overlapping ranges of

concentrations," but even if some of the compositions encompassed by Evans' broad disclosure might have a viscosity of 150 cSt at 40° C, that possibility is not adequate to support a finding of inherent anticipation.

"Inherency . . . may not be established by probabilities or possibilities. The mere fact that a certain thing *may* result from a given set of circumstances is not sufficient." *In re Oelrich*, 666 F.2d 578, 581 (CCPA 1981). *See also Ex parte Skinner*, 2 USPQ2d 1788, 1789 (BPAI 1986) ("[T]he examiner must provide some evidence or scientific reasoning to establish the reasonableness of the examiner's belief that the functional limitation is an inherent characteristic of the prior art" before the burden is shifted to the applicant to disprove the inherency.).

The Examiner has not provided evidence or scientific reasoning to show that any specific composition disclosed by Evans is within the scope of the instant claims, and therefore has not made out a case of inherent anticipation by Evans. The Examiner's finding that "Evans anticipates the limitations of the instant claims" (FF7, Ans. 5) is not supported by the evidence of record. The Examiner also has not shown that Taki discloses a composition that expressly or inherently meets all the limitations of the instant claims. We therefore reverse the rejection for anticipation based on Taki.

The Examiner's obviousness rejections are based on the reasoning that a person of ordinary skill in the art "would have been motivated to optimize the viscosity of the Evans' [and Greff '767's and Taki's] final formulation[s], because he would have had a reasonable expectation of

success in achieving the safest clinical outcome and avoiding transvenous passage" of the embolizing composition (FF9, FF10; Ans. 6-8).

The Examiner has not made out a prima facie case that the claimed compositions would have been obvious based on the teachings of Evans, Greff '767, or Taki. While "the discovery of an optimum value of a variable in a known process is normally obvious," *In re Antonie*, 559 F.2d 618, 620 (CCPA 1977), this is not always the case. One exception to the rule is where the parameter optimized was not recognized in the prior art as one that would affect the results. *Id.*

Here, the Examiner has not pointed to any teaching in the cited references, or provided any explanation based on scientific reasoning, that would support the conclusion that those skilled in the art would have considered it obvious to "optimize" the prior art compositions by increasing their viscosity to the level recited in the claims. No reason to have done so is apparent to us based on the record. On the contrary, the references all suggest that low viscosity was a desired property in embolic compositions. Evans teaches that a preferred composition has a viscosity of 60 centipoise or less at 20° C (FF12). Appellants calculate, and the Examiner does not dispute, that 60 centipoise at 20° C corresponds to less than 75 cSt at 40° C (App. Br. 12). Therefore, Evans' preferred composition has a viscosity less than half of that required by the instant claims.

Likewise, Greff '767 teaches that a composition with a viscosity of 145 cSt at 20° C had "physical properties which make[ ] injection . . . into vascular sites significantly more difficult" (FF20, FF22) – and the only physical property of the composition discussed is its viscosity. In agreement

with the other references, Taki teaches that its composition had a low viscosity (FF24) and had the desirable property of being easily injected through a microballoon catheter (FF24).

Thus, the references teach that low viscosity is a desirable characteristic for embolic compositions. In our view, none of the cited references would have led a person of ordinary skill in the art to modify the known embolic compositions by increasing their viscosity to at least 150 cSt at 40° C. The Examiner has not adequately explained why such a modification would have been obvious.

The U.S. Supreme Court recently held that rigid and mandatory application of the "teaching-suggestion-motivation," or TSM, test is incompatible with its precedents. *KSR Int'l Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1741 (2007). The Court did not, however, discard the TSM test completely; it noted that its precedents show that an invention "composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art." *Id.*

The Court held that the TSM test must be applied flexibly, and take into account a number of factors "in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed." *Id.* at 1740-41. Despite this flexibility, however, the Court stated that "it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the [prior art] elements in the way the claimed new invention does." *Id.* "To facilitate review, this analysis should be made explicit." *Id.*

The obviousness rationale addressed in *KSR* was premised on combining elements known in the prior art. *Id.* at 1738-39. A parallel analysis applies, however, to a rejection premised on the obviousness of modifying a known composition to change its properties.

The *KSR* Court noted that obviousness cannot be proven merely by showing that the elements of a claimed device were known in the prior art; it must be shown that those of ordinary skill in the art would have had some "apparent reason to combine the known elements in the fashion claimed." *Id.* at 1741.

In the same way, when the prior art teaches away from the claimed solution as presented here (FF12, FF20, FF22 and FF 24), obviousness cannot be proven merely by showing that a known composition could have been modified by routine experimentation or solely on the expectation of success; it must be shown that those of ordinary skill in the art would have had some apparent reason to modify the known composition in a way that would result in the claimed composition.

The Examiner has not persuasively explained why a person of ordinary skill in the art would have had a reason to modify the compositions taught by Evans, Greff '767, or Taki in a way that would result in the compositions defined by the claims on appeal. Therefore, the Examiner has not made out a prima facie case of obviousness under 35 U.S.C. § 103. We reverse the rejections of claims 1-13 and 15-17 as obvious in view of Evans; the rejection of claims 1-17 as obvious in view of Greff '767; and the rejection of claims 1-6, 9, 10, and 14-17 as anticipated by or obvious in view of Taki.

SUMMARY

The rejections on appeal are not supported by a preponderance of the evidence in the record and are therefore reversed.

REVERSED

Ssc:

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